

**WE CLAIM:**

- 1        1. A stable bupropion hydrochloride tablet, wherein the tablet is free of stabilizer  
2            and contains at least about 80% of undegraded bupropion hydrochloride after  
3            storage for two months at 40°C and 75% relative humidity.
- 1        2. The tablet according to claim 1, wherein the tablet is a sustained release tablet.
- 1        3. The tablet according to claim 1, wherein the tablet comprises bupropion  
2            hydrochloride, one or more release rate controlling polymers, and one or more  
3            diluents, binders, lubricants, glidants and coloring agents.
- 1        4. The tablet according to claim 3, wherein the release rate controlling polymers  
2            comprises one or more of cellulose derivatives, acrylates,  
3            polyvinylacetate/povidone mixtures, polyethylene oxides, starches and their  
4            derivatives, gums, alginates, carbohydrate based polymers, polysaccharide, and  
5            combinations thereof.
- 1        5. The tablet according to claim 4, wherein the cellulose derivative comprises one  
2            or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,  
3            hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose,  
4            sodium carboxymethylcellulose, and combinations thereof.
- 1        6. The tablet according to claim 5, wherein the cellulose derivative comprises  
2            hydroxypropyl cellulose.
- 1        7. The tablet according to claim 4, wherein the acrylate comprises one or more of  
2            carbomer, polycarbophil, and EUDRAGIT®.
- 1        8. The tablet according to claim 7, wherein the carbomer comprises one or more of  
2            Carbopol® -971 P, 974 P, and 934 P.
- 1        9. The tablet according to claim 3, wherein the binder comprises one or more of  
2            starch, gelatin, highly dispersed silica, mannitol, lactose, polyethylene glycol,  
3            polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, cross-linked

- 4 carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl  
5 cellulose and natural, and synthetic gums.
- 1 10. The tablet according to claim 3, wherein the diluent comprises microcrystalline  
2 cellulose.
- 1 11. The tablet according to claim 3, wherein the lubricant comprises stearic acid.
- 2 12. A method of stabilizing bupropion hydrochloride tablets using a dry granulation  
3 process, the dry granulation process comprising:  
4 a) blending bupropion hydrochloride and one or more pharmaceutically  
5 acceptable excipient(s),  
6 b) compacting or slugging the material of step (a),  
7 c) sizing the compacted or slugged material of step (b) into granules, and  
8 d) compressing the granules of step (c).
- 1 13. The method according to claim 12, wherein the tablet contains at least about 80%  
2 of undegraded bupropion hydrochloride after storage for two months at 40°C and  
3 75% relative humidity.
- 1 14. The method according to claim 12, wherein step (b) comprises compaction.
- 1 15. The method according to claim 14, wherein the compaction comprises using a  
2 roller compactor.
- 1 16. The method according to claim 12, wherein step (c) comprises milling.
- 2 17. The method according to claim 12, further comprising lubricating the sized  
3 granules of step (c) before compressing the granules.
- 1 18. The method according to claim 12, further comprising coating the tablet after  
2 compressing the granules.

- 1 19. The method according to claim 12, wherein the one or more pharmaceutically  
2 acceptable excipients comprise one or more of release rate controlling polymers,  
3 diluents, binders, lubricants, glidants, and coloring agents.
- 1 20. The method according to claim 19, wherein the release rate controlling polymers  
2 comprise one or more of cellulose derivatives, acrylates,  
3 polyvinylacetate/povidone mixtures, polyethylene oxides, starches and their  
4 derivatives, gums, alginates, carbohydrate based polymers, polysaccharide, and  
5 combinations thereof.
- 1 21. The method according to claim 20, wherein the cellulose derivative comprises  
2 one or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,  
3 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose,  
4 sodium carboxymethylcellulose, and combinations thereof.
- 1 22. The method according to claim 21, wherein the cellulose derivative comprises  
2 hydroxypropyl cellulose.
- 1 23. The method according to claim 20, wherein the acrylate comprises one or more  
2 of carbomer, polycarbophil, and EUDRAGIT®.
- 1 24. The method according to claim 23, wherein carbomer comprises one or more of  
2 Carbopol® -971 P, 974 P and 934 P.
- 1 25. The method according to claim 19, wherein the binder comprises one or more of  
2 from starch, gelatin, highly dispersed silica, mannitol, lactose, polyethylene  
3 glycol, polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, cross-linked  
4 carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl  
5 cellulose, and natural or synthetic gums.
- 1 26. The method according to claim 19, wherein the diluent comprises  
2 microcrystalline cellulose.
- 1 27. The method according to claim 19, wherein the lubricant comprises stearic acid.

- 1 28. The method according to claim 12, wherein the bupropion hydrochloride tablets  
2 are free of stabilizer.
- 1 29. A method of one or both of treating depression and providing smoking cessation,  
2 the method comprising:
- 3 providing bupropion hydrochloride in a dosage form,  
4 wherein the dosage form is free of stabilizer and contains at least about 80% of  
5 undegraded bupropion hydrochloride after storage for two months at 40°C and  
6 75% relative humidity.
- 1 30. The method of claim 29, wherein the dosage form is produced using a dry  
2 granulation process, the dry granulation process comprising (a) blending  
3 bupropion hydrochloride and one or more pharmaceutically acceptable  
4 excipients, (b) either compacting or slugging the blend of step (a), sizing the  
5 compacted or slugged material of step (b) into granules, and (d) compressing the  
6 granules of step (c).